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SECTION 8
510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K130141.

807.92 (a)(1): Name: Hitachi Chemical Diagnostics
Address: 630 Clyde Court
Mountain View, CA 94043

Phone: (650) 961 5501
FAX: (650) 969 2745
Contact: Mr. Charles Tsou

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name:
S TEST Reagent Cartridge Alkaline Phosphatase (ALP)

Common Name: Routine chemistry analyzer for ALP

Classifications: 21 CFR § 862.1050 Alkaline Phosphatase (ALP)

807.92 (a)(3): Identification of the legally marketed predicate devices

Cobas c systems ALP2 (Roche Diagnostics, Inc., Indianapolis, IN)- K100853

807.92 (a)(4): Device Description
The Hitachi Clinical Analyzer is an automatic, bench-top, wet chemistry system intended for use in clinical laboratories or physician office laboratories. The instrument consists of a desktop analyzer unit, an operations screen that prompts the user for operation input and displays data, a printer, and a unit cover. The analyzer unit includes a single probe, an incubation rotor, carousels for sample cups and reagent cartridges, and a multi-wavelength photometer. The single-use reagent cartridges may be placed in any configuration on the carousel, allowing the user to develop any test panel where the reagent cartridges are available.

The S TEST reagent cartridges are made of plastic and include two small reservoirs capable of holding two separate reagents (R1 and R2), separated by a reaction cell/photometric cuvette. The cartridges also include a dot code label that contains all chemistry parameters, calibration factors, and other production-related information, e.g., expiration dating. The dimensions of the reagent cartridges are: 13.5 mm (W) × 28 mm (D) × 20.2 mm (H).

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System operation: After the sample cup is placed into the carousel, the analyzer pipettes the sample, pipettes the reagent, and mixes (stirs) the sample and reagent together. After the sample and reagent react in the incubator bath, the analyzer measures the absorbance of the sample, and based on the absorbance of the reactions, it calculates the concentration of analyte in the sample. The test system can measure analytes in serum or plasma and results are available in approximately 15 minutes per test. This submission is for Reagent Cartridge ALP.

Chemistry reactions: Alkaline phosphatase (ALP) in the sample reacts with its substrate, p-nitrophenyl phosphate (p-NPP), in ethylaminoethanol (EAE) buffer, to release p-nitrophenol (yellow). The ALP activity is determined by measuring the rate of p-nitrophenol production.

807.92 (a)(5): Intended Use

The S TEST Reagent Cartridge Alkaline Phosphatase (ALP) is intended for the quantitative measurement of alkaline phosphatase activity in serum, lithium heparinized plasma, or sodium citrate plasma using the HITACHI Clinical Analyzer. The S TEST Reagent Cartridge Alkaline Phosphatase (ALP) is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Measurements of alkaline phosphatase are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

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807.92 (a)(6): Technological Similarities and Differences to the Predicate
The following chart describes similarities and differences between the two test systems.

Characteristic	Hitachi S TEST Systems	PREDICATE
Instrument Platform	Hitachi Clinical Analyzer (originally cleared under K111753)	Roche cobas c systems – K100853
Alkaline Phosphatase (ALP)	K number- pending	Roche K number- K100853
Device Class, Regulation Code	Class II, 21 CFR 862.1050	Same
Classification Product Code	CJE	CJE
Intended Use	Quantitative determination of ALP	Same
Testing Environment	Physician office or clinical lab	Clinical lab
Test Principle	In the presence of magnesium ions, ALP reacts with p-NPP to release p-nitrophenol.	In the presence of magnesium and zinc ions, p-NPP is cleaved by phosphatases into phosphate and p-nitrophenol
Specimen Type	Human serum or plasma	Same
Reportable Range	10 to 1,000 U/L	5 to 1,200 U/L
Detection Wavelength	405/508 nm	480/450 nm
Detection Limit	5 U/L	Same
Linearity	5 to 1,000 U/L	5 to 1,200 U/L
Precision	%CVs range from 4.4% to 5.8%	%CVs range from 0.6% to 2.4%

807.92 (b)(1): Brief Description of Nonclinical Data
A series of studies were performed that evaluated the following nonclinical performance characteristics for each analyte: analytical sensitivity (limits of detection), linearity, 20-day in-house precision, interference testing, in-house method comparisons, and matrices comparison between serum and heparin plasma.

Analytical Sensitivity (Limits of Detection)
The study followed CLSI EP17-A, and the limit of detection was found to be 1.8 U/L

Linearity
The study followed CLSI EP-6A, and the range of linearity was 5 U/L to 1,000 U/L.

20-day In-house Precision
The studies followed CLSI EP5-A2, where three levels of samples were each tested in two runs, twice a day, for 20 days. The results were as follows:

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Precision Summary:

ALP- Low, Level 1, Summary

ALP	Within-Run	Total
Mean (U/L)	42.7	42.7
SD (U/L)	1.30	2.25
%CV	3.1%	5.3%

ALP- Middle, Level 2, Summary

ALP	Within-Run	Total
Mean (U/L)	80.5	80.5
SD (U/L)	3.07	4.65
%CV	3.8%	5.8%

ALP- High, Level 3, Summary

ALP	Within-Run	Total
Mean (U/L)	555.6	555.6
SD (U/L)	13.99	24.69
%CV	2.5%	4.4%

Interference Testing (per CLSI EP7-A2)
The data demonstrated that the ALP test system was not affected by high levels of the following substances at the levels noted:

Hemoglobin: no interference up to 500 mg/dL
Unconjugated bilirubin: no interference up to 50 mg/dL
Lipemia: no interference up to 2,000 mg/dL
Ascorbic acid: no interference up to 50 mg/dL

Lack of interference was defined as recoveries between 90% and 110% of the neat value, and assay performance claims were established on the HITACHI Clinical Analyzer by testing two serum pools containing approximately 12 mg/L and 80 U/L ALP.

Method Comparison
A total of 97 clinical specimens spanning the dynamic range (11 to 926 U/L), were assayed in singleton and in a blinded fashion by both the Hitachi system and a standard laboratory system. The comparative data were analyzed by linear regression and are shown below. (CI = confidence interval)

ALP Regression Statistics:

n	r	Slope (95% CI)	y-intercept (95% CI)	X mean	Y mean
97	0.996	0.926 (0.909 to 0.943)	4.8 (-0.2 to 9.8)	203 U/L	193 U/L

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Matrices Comparisons

A study was performed to validate the use of two plasma types as an alternative to serum for the Hitachi Clinical Analyzer with S TEST Reagent Cartridge Alkaline Phosphatase (ALP). The plasma types were sodium citrate and lithium heparin. Thirty-eight (38) matched serum/plasma samples that spanned the dynamic range (13 to 967) were assayed in singleton and the results were compared using linear regression (plasma = y-axis, each type). The performance characteristics were as follows.

N = 38

Range (serum) = 13 to 967 U/L

	Sodium Citrate Plasma	Heparinized Plasma
Slope (95% CIs)	1.03 (1.01 to 1.05)	1.01 (1.00 to 1.02)
y-intercept (95% CIs)	-11.2 (-15.5 to -7.0)	-5.4 (-8.3 to -2.6)
r	0.999	0.999

807.92 (b)(2): Brief Description of Clinical Data

Studies for precision and method comparison (accuracy) were performed at three external POL-type sites to evaluate the Hitachi Clinical Analyzer with S TEST Reagent Cartridges Alkaline Phosphatase (ALP) in one of its targeted intended use environments, the physician's office laboratory.

For the external site precision study, each site received three blinded serum samples (the Precision Panel, labeled A, B, and C) that were chosen to represent low, middle, and high concentrations of ALP. Each sample was assayed six times per day for five days, reporting 30 results per level. Precision estimates for total precision were as follows:

ALP (U/L)
n = 30 replicates per sample per site

Site	Sample	Mean	Total Precision	
			SD (U/L)	%CV
Site 1	Low	13.2	0.96	7.3%
Site 2	Low	12.8	1.00	7.8%
Site 3	Low	13.4	1.23	9.2%
Site 1	Middle	76.2	2.26	3.0%
Site 2	Middle	68.8	5.24	7.6%
Site 3	Middle	70.0	6.28	9.0%
Site 1	High	408.6	26.01	6.4%
Site 2	High	390.1	23.21	6.0%
Site 3	High	402.9	12.33	3.1%

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For the external site method comparison study, a series of approximately 70 serum specimens with ALP values ranging from 11 to 745 U/L were assayed on the Hitachi Clinical Analyzer at three sites using S TEST Reagent Cartridge Alkaline Phosphatase (ALP) (y) and a comparative method as the reference method (x). Linear regression analysis (least squares) yielded the following results:

POL ACCURACY DATA SUMMARY- ALP (U/L)

Site #	n	Hitachi Range	Regression Equation	"r"	95% CI Slope	95% CI Intercept
1	77	13 to 745	y = 0.967x + 2.9	0.99	0.949 to 0.984	-0.6 to 6.4
2	72	11 to 688	y = 0.942x - 0.7	0.99	0.925 to 0.960	-4.4 to 2.9
3	72	12 to 736	y = 0.980x + 0.8	0.99	0.961 to 0.999	-3.2 to 4.7

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

Nonclinical and clinical testing was performed for the Hitachi Clinical Analyzer with S TEST Reagent Cartridge Alkaline Phosphatase (ALP). The test system was shown to be safe and effective for its intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

March 22, 2013

Hitachi Chemical Diagnostics, Inc.
c/o Erika Ammirati
630 Clyde Court
Mountain View, CA 94043

Re: k130141
Trade/Device Name: S TEST Reagent Cartridge Alkaline Phosphatase (ALP)
Regulation Number: 21 CFR §862.1050
Regulation Name: Alkaline Phosphatase or isoenzymes test system
Regulatory Class: Class II
Product Code: CJE
Dated: January 18, 2013
Received: January 22, 2013

Dear Ms. Ammirati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130141

Device Name:
S TEST Reagent Cartridge Alkaline Phosphatase (ALP)

Indications for Use:
The S TEST Reagent Cartridge Alkaline Phosphatase (ALP) is intended for the quantitative measurement of alkaline phosphatase activity in serum, lithium heparinized plasma, or sodium citrate plasma using the HITACHI Clinical Analyzer. The S TEST Reagent Cartridge Alkaline Phosphatase (ALP) is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Measurements of alkaline phosphatase are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health (OIR)

510(k) k130141